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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/857,078  | 09/24/2001  | Rafael Pi Subirana   | H-3734 PCTUS        | 9173             |
| 23657   | 7590        | 08/19/2004           | EXAMINER            |                  |
| COGNIS CORPORATION<br>PATENT DEPARTMENT<br>300 BROOKSIDE AVENUE<br>AMBLER, PA 19002 |             |                      | BADIO, BARBARA P    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1616                |                  |

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/857,078

Applicant(s)

PI SUBIRANA ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-30 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-20 is/are allowed.
- 6) ☒ Claim(s) 21-26, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 27-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**First Office Action on the Merits of a RCE**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

**3. The rejections of claims 21 and 22 under 35 USC 102(b) over Cremlyn et al. or Ramirez et al. are maintained.**

Applicant argues the amended claim language excludes the presence of impurities or by-products produced by the prior art processes. According to applicant the differences in the processes used to make the products result in differences in the end products themselves. Applicant's argument was considered but not persuasive for the following reasons.

As stated in previous Office Actions, the patentability of the product is not dependent on the process by which it is produced. The claims as amended are drawn to a product consisting essentially of a sterol phosphate. The prior art teaches products consisting essentially of a sterol phosphate and, thus, anticipates the claimed products.

Applicant's argument that differences in the processes used to make the products would result in differences in the end products themselves is noted. However, the instant claims do not recite that which would make the claimed product different from that taught by the prior art nor is there any evidence of record showing the claimed product is different from the product taught by the prior art.

For these reasons and those given in previous Office Actions, the rejections of claims 21 and 22 under 35 USC 102(b) over Cremlyn et al. or Ramirez et al. are maintained.

4. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lion Dentifrice Co. Ltd. (JP 49108065).

Lion Dentifrice Co. Ltd. teaches saturated steroid alcohol phosphates or their salts such as cholesterol phosphate and cholestanol phosphate (see attached English Abstract). The products taught by the reference are encompassed by the instant claims.

5. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lion Dentifrice Co. Ltd. (JP 52102441).

Lion Dentifrice Co. Ltd. teaches compositions containing cholestanol phosphate or salts thereof and epicholestanol phosphate or salts thereof (see attached English Abstract and page 247, formulae 1 and 2). The products taught by the reference are encompassed by the instant claims.

6. Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kudo et al. (US 3,974,188).

Kudo et al. teach cholestanyl and epicholestanyl phosphates and pharmaceutical compositions containing said (see the entire article, especially col. 6, lines 12-33). The reference teaches the application of the compounds to affected parts can also be accomplished by using them in the form of ointments, lotions, creams, powders and aerosol sprays for the skin (see especially col. 6, lines 19-33). The products and compositions taught by the reference are encompassed by the instant claims.

7. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al.

Watanabe et al. teach phosphate esters such as cholesterol phosphate (see the entire article, especially page 7408, Scheme 1). The product taught by the reference is encompassed by the instant claim.

***Claim Rejections - 35 USC § 103***

8. The rejection of claims 23-26, 29 and 30 under 35 USC 103(a) over Simonnet ('433) and Ribier et al. ('250) in combination is maintained.

Applicant argues the cited references fail to teach or suggest the claimed cosmetic composition. According to applicant (a) Simonnet does not teach or suggest the addition of a sterol phosphate to an already formed cosmetic formulation base and that the only reason the skilled artisan would be motivated to incorporate an amphiphilic lipid into a composition would be if that composition contained lamellar based lipid vesicles which could be stabilized by the incorporation of such an additional lipid and there is no motivation towards the selection of cholesterol phosphates over any other amphiphilic lipid and (b) Ribier fails to remedy the deficiencies of Simonnet and does not provide the skilled artisan with either a teaching, suggestion or motivation to prepare a cosmetic composition by combining a formulation based and a sterol phosphate.

Applicant's argument was considered but not persuasive for the following reasons.

The issue is not whether the prior art reason for incorporation of a sterol phosphate into a cosmetic preparation but whether said prior art makes obvious a cosmetic preparation comprising a sterol phosphate. The prior art teaches a cosmetic composition containing said sterol phosphate. It is the examiner's position that the cited prior art makes obvious the incorporation of said sterol phosphate into a cosmetic formulation by its teachings of the utilization a sterol phosphate into cosmetic preparations. How said incorporation occurs is irrelevant to the claimed invention.

Applicant's argument that there is no motivation to include an amphiphilic lipid outside a lamellar lipid bilayer comprising a silicone surfactant is also noted. The examiner notes that said surfactants are utilized in cosmetic formulations and, thus, are encompassed by the claimed invention.

With regards to claims 29 and 30, applicant argues the cited references further fail to teach or suggest the application of an odor-suppressing effective amount of the cosmetic preparation to an area of the body to be deodorized. However, application of an effective amount of a cosmetic preparation such as a deodorant to an area needing to be deodorized is done routinely.

For these reasons and those given in previous Office Actions, the rejection of claims 23-26, 29 and 30 under 35 USC 103(a) over Simonnet ('433) and Ribier et al. ('250) in combination is maintained.

9. Claims 24-26, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kudo et al. (US 3,974,188); Simonnet ('433) and Ribier et al. ('250) in combination.

Kudo et al. teach cholestanyl and epicholestanyl phosphates and pharmaceutical compositions containing said (see the entire article, especially col. 6, lines 12-33). The reference teaches the application of the compounds to affected parts can also be accomplished by using them in the form of ointments, lotions, creams, powders and aerosol sprays for the skin (see especially col. 6, lines 19-33).

Simonnet et al. teach a stable dispersion containing a lipid vesicle comprising a lamellar phase formed of at least one silicone surfactant (see the entire article, especially col. 1, lines 61-66). The reference also teaches (a) that it is advantageous to add an ionic amphiphilic lipid such as the alkali metal salts of cholesterol phosphate because it enhances the stability of the dispersion by inhibiting flocculation (see col. 3, lines 24-38), (b) the amphiphilic ionic lipids are present at concentrations ranging from 0 to 20% by weight of the silicone surfactant (col. 3, lines 58-61) and (c) the vesicles may contain one or more active compounds, such as, cosmetic and/or dermatological active agents such as antibacterial agents, antiperspirants, deodorants etc. (see col. 4, line 20 – col. 5, line 50).

Ribier et al. teach a cosmetic composition containing a dispersion of vesicles formed from a lipid-phase membrane containing at least one ionic and/or nonionic amphiphilic lipid encapsulating an aqueous phase and at least one agent that stabilizes said vesicles (see the entire article, especially col. 5, line 65 - col. 6, line 27; col. 10, lines 26-37; claims 7 & 18). The reference teaches ionic amphiphilic lipids such as cholesterol acid phosphate and its alkali metal salts (see col. 8, line 45 - col. 9, line 6).

Based on the teachings of the above-cited references, the incorporation of cholesterol acid phosphate or its alkali metal salts in cosmetic compositions would have been obvious to the skilled artisan at the time of the present invention. The motivation to add cholesterol acid phosphate or its alkali metal salts to cosmetic compositions is based on the prior art teachings that ionic amphiphilic lipids provide stability to dispersions contained in compositions such as cosmetic composition.

Claims 24 and 30 further differ from the prior art by reciting a cosmetic preparation containing a specific amount of sterol phosphate.

Claim 29 further differs from the prior art by reciting the application of an odor-suppressing effective amount of the cosmetic preparation to an area of the body to be deodorized.

The recitation of (a) an amount of sterol phosphate in a cosmetic preparation or (b) the application of an odor-suppressing effective amount of a cosmetic preparation to an area of the body to be deodorized is prima facie obvious. Said recitation is not patentable because the formulation of various preparations having various amount of sterol phosphate or the application of odor-suppressing effective amount of the cosmetic preparation to an area of the body to be deodorized would be within the level of skill of the ordinary artisan in the art. The motivation to add various amount of said sterol phosphate is based on the desire to find an amount of said compound having optimum effect as taught by Simonnet.

***Allowable Subject Matter***

10. Claims 10-20 are allowed.

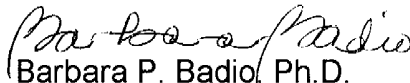
11. Claims 27 and 28 are objected to as being dependent upon a rejected base claim.

***Telephone Inquiry***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
August 18, 2004